



**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations (ID 1648, 1700) pursuant to Article 13(1) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations (ID 1648, 1700) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food that is the subject of the health claim is red yeast rice (i.e. rice fermented with the red yeast *Monascus purpureus*). The Panel considers that, whereas red yeast rice is not sufficiently characterised in relation to the claimed effect, the food constituent, monacolin K from red yeast rice, is sufficiently characterised.

The claimed effects are “cholesterol” and “cholesterol management/heart health”. The target population is assumed to be adults in the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to maintenance of normal blood LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that two randomised controlled trials provided from which conclusions could be drawn for the scientific substantiation of the claim showed an effect of red yeast rice preparations providing a daily dose of about 10 mg monacolin K on LDL-cholesterol

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-2384, EFSA-Q-2008-2436, adopted on 30 June 2011.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

concentrations in individuals with hypercholesterolaemia, that the effect of pure monacolin K on LDL-cholesterol concentrations is well established and that the mechanism by which monacolin K can contribute to the claimed effect is well known.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL- cholesterol concentrations.

The Panel considers that in order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily. The target population is adults in the general population.

In relation to restrictions of use, the Panel refers to the Summary of Product Characteristics of lovastatin-containing medicinal products available on the EU market.

#### **KEY WORDS**

Monacolin K, *Monascus purpureus*, red yeast rice, LDL-cholesterol, health claims.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent (ID 1648, 1700)

The food that is the subject of the health claim is red yeast rice (i.e. rice fermented with the red yeast *Monascus purpureus*).

Red yeast rice is a traditional Chinese food product which is still a dietary staple in many Asian countries (Heber et al., 1999). Various red yeast rice preparations are available as food supplements. The preparations from red yeast rice typically contain starch, protein, fat (including monounsaturated fatty acids, plant sterols), isoflavones, and other compounds. Depending on the *Monascus* strains used and the fermentation conditions, the products may contain polyketides called monacolins, which are secondary metabolites produced during fermentation (Liu et al., 2006).

Monacolin K, in lactone (also known as lovastatin or mevinolin) and hydroxy acid forms, is the main monacolin in *Monascus purpureus*-fermented rice (75-90 % of total monacolin content) (Heber et al., 1999; Li et al., 2004). Commercial red yeast rice products have variable contents of monacolin K and total monacolins (Gordon et al., 2010; Li et al., 2004).

From the conditions of use provided, the Panel notes that monacolin K from *Monascus purpureus*-fermented rice has been specified as the food constituent which may be responsible for the claimed effect considered in this opinion. Monacolin K from *Monascus purpureus*-fermented rice is a well defined compound, which can be measured in foods by established methods.

The Panel considers that, whereas red yeast rice is not sufficiently characterised in relation to the claimed effect, the food constituent, monacolin K from red yeast rice, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health (ID 1648, 1700)

The claimed effects are “cholesterol” and “cholesterol management/heart health”. The Panel assumes that the target population is adults in the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to maintenance of normal blood LDL-cholesterol concentrations.

<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>5</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.14 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

### 3. Scientific substantiation of the claimed effect (ID 1648, 1700)

Among the references provided were an editorial of a scientific journal, letters-to-the-editor, monographs, and narrative reviews on *Monascus purpureus*, red yeast rice supplements or 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors, which did not contain original data that could be used for the scientific substantiation of the claim. Some studies did not address the food which is the subject of the claim but rather other foods (e.g. arginine) or did not address blood lipids as an outcome but rather other outcomes (e.g. bioavailability of monacolin K from fermented red yeast rice). One pilot study compared the effect of a combination of *Monascus purpureus* extract, octacosanols and niacin with pravastatin on blood cholesterol concentrations. The Panel considers that no conclusions can be drawn from a study using a combination of food constituents for the substantiation of a health claim on monacolin K from red yeast rice alone. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One systematic review and some human intervention studies investigated the effect of red yeast rice preparations on blood cholesterol concentrations but did not report the monacolin K content of the preparations used. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A meta-analysis of randomised clinical trials which investigated the effect of fermented red yeast rice preparations on blood lipid concentrations in subjects with primary hyperlipidaemia was provided (Liu et al., 2006). The Panel notes that the meta-analysis reported to include studies of poor methodological quality (lack of information on randomisation, blinding, drop-outs) and considers that no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claim.

Eight of the studies identified in the meta-analysis evaluated the effect of fermented red yeast rice preparations against placebo on blood LDL-cholesterol concentrations. Seven studies were published in Chinese and no translation in an EU language was available to the Panel. The remaining study is described below (Heber et al., 1999).

Two human intervention studies (Heber et al., 1999; Lin et al., 2005) investigated the effect of red yeast rice preparations with known monacolin K content on total and LDL-cholesterol concentrations.

In a double-blind, randomised, placebo-controlled trial (RCT) (Heber et al., 1999), 88 subjects with hypercholesterolaemia, who were not taking lipid-lowering medications, received either fermented red yeast rice (Cholestin, 2.4 g/day) or a placebo (rice powder) in capsules daily for 12 weeks. The fermented red yeast rice preparation contained 0.3 % monacolin K (0.2 % in lactone form, 0.1 % in hydroxy acid form) by weight, corresponding to a daily dose of around 7.5 mg. The content of other monacolins was 0.1 %, i.e. 2.5 mg/day. A total of 83 subjects completed the study (n=42 in the treatment group vs. n=41 in the placebo group; 46 men and 37 women, 34-78 years). Significant differences between groups were observed at weeks 8 and 12 for LDL-cholesterol concentrations (p<0.001 at both time points, per protocol (PP) analysis) and total cholesterol concentrations (p<0.05 at both time points, PP analysis). ANCOVA showed main effects of baseline LDL-cholesterol/total cholesterol concentrations and treatment group on LDL-cholesterol/total cholesterol concentrations respectively at 12 week (p<0.001 for all). At week 12, the mean LDL-cholesterol concentrations in the treatment group was reduced by 22 % from baseline, compared with a 3 % reduction in the

placebo group. The mean total cholesterol concentration was reduced by 16 % in the treatment group compared to 2 % in the placebo group.

In a double-blind RCT (Lin et al., 2005), 79 subjects with hypercholesterolaemia who were not taking lipid-lowering medications during the trial, received either fermented red yeast rice (*Monascus purpureus* Went rice, 1.2 g/day) or a placebo (grounded rice) daily for eight weeks. Patients taking lipid-lowering medications were considered after a four-week wash-out period, with the exception of probucol, which had to be discontinued for at least six months. The fermented red yeast rice preparation contained 0.95 % lovastatin by weight corresponding to a daily dose of around 11.4 mg. The Panel assumes that this dose corresponds to monacolin K in the lactone form only. The amount of monacolin K in its hydroxy acid form was not provided. The preparation also contained 0.21 % other monacolins by weight, i.e. 2.5 mg/day. A total of 75 subjects completed the study (n=38 in treatment group, 59 % men, vs. n=37 in placebo group, 55 % men; 23-65 years). At week eight, a significantly greater reduction in LDL-cholesterol concentrations was observed in the treatment group compared to the placebo group (-26.3 % vs. -1.4 %,  $p<0.001$ , intention-to-treat (ITT) analysis). The reduction in total cholesterol concentrations was also significantly higher in the treatment group than in the placebo group (-20.4 % vs. -0.4 %  $p<0.001$ , ITT analysis).

Pure monacolin K (lovastatin) has been shown to be effective in reducing total cholesterol and LDL-cholesterol concentrations in individuals with hypercholesterolaemia and is a well-known inhibitor of HMG-CoA reductase. A significant inhibitory effect of a fermented red yeast rice preparation (Cholestin) on HMG-CoA reductase activity and cholesterol concentrations was observed *in vitro* in human hepatic cells (HepG2) (Man et al., 2002).

In weighing the evidence, the Panel took into account that two RCTs provided from which conclusions could be drawn for the scientific substantiation of the claim showed an effect of red yeast rice preparations providing a daily dose of about 10 mg monacolin K on LDL-cholesterol concentrations in individuals with hypercholesterolaemia, that the effect of pure monacolin K on LDL-cholesterol concentrations is well established and that the mechanism by which monacolin K can contribute to the claimed effect is well known.

The Panel concludes that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations.

#### **4. Panel's comments on the proposed wording (ID 1648, 1700)**

The Panel considers that the following wording reflects the scientific evidence: "Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations".

#### **5. Conditions and possible restrictions of use (ID 1648, 1700)**

The Panel considers that in order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily. The target population is adults in the general population.

In relation to restrictions of use, the Panel refers to the Summary of Product Characteristics of lovastatin-containing medicinal products available on the EU market.



## CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, red yeast rice, which is the subject of the health claim is not sufficiently characterised in relation to the claimed effect, whereas the food constituent monacolin K from red yeast rice is sufficiently characterised.
- The claimed effects are “cholesterol” and “cholesterol management/heart health”. The target population is assumed to be adults in the general population. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations.
- The following wording reflects the scientific evidence: “Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations”.
- In order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily. The target population is adults in the general population.
- In relation to restrictions of use, reference is made to the Summary of Product Characteristics of lovastatin-containing medicinal products available on the EU market.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2384, EFSA-Q-2008-2436). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>6</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>7</sup>

Foods are commonly involved in many different functions<sup>8</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

## APPENDIX C

Table 1. Main entry health claims related to monacolin K from red yeast rice, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1648	Red yeast rice ( <i>Monascus Purpureus</i> / Ang-Khak).	Cholesterol.	Contributes to maintain a healthy cholesterol in the framework of a healthy balanced diet / supports healthy cholesterol.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 200 mg red yeast rice (rice fermented by <i>Monascus purpureus</i>) assayed for Monacoline equivalent to 3 mg monacoline per day</li> <li>- Adult dosage: 600-2400 mg taken daily (usually in two doses) for at least 8 weeks. Formulations should be standardised to specific amounts of total monacolin or monacolin K. Precautions: Use cautiously in persons taking blood thinning agents or in those with suppressed co-enzyme Q10. Do not use if on statin medication. Anyone with raised blood cholesterol or triglyceride levels should seek advice from a healthcare provider before using this product.</li> <li>- Food supplement with 1.2-2.4g of red rice (of which 4.8-9.6mg is monacholine K), 600-1200 µg of folic acid, 6-12 mg of vitamin B6 and 3-6 µg of vitamin B12 in the daily dose.</li> <li>- The recommended dosage for the red yeast rice product (Wearnes Biotech &amp; Medicals, Singapore) is 2400 mg/day (this is equivalent to 5 mg/day of monacolin K). No adverse effects reported. Do not take more than the recommended dosage of the red yeast rice product in any 24 hour period. Keep out of the reach of children. Not recommended for people under the age of 20. Women should not take the red yeast rice product if they are pregnant, intend to be pregnant or breast feeding. Not recommended for people at risk of or have a history of liver disease. Do not consume grapefruit juice with the red yeast rice product. Do not take the red yeast rice product if you consume more than 2 units of alcohol per day; if you have a serious infection; if you have undergone an organ transplant; if you have a serious disease or physical disorder or if you have undergone major surgery recently. Consult your doctor if you are taking any medication or if you are under physician supervision for cholesterol control.</li> <li>- Citirizinfrei–Erwachsene–Tagesdosis Rotreis: 990 mg.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1700	<i>Monascus purpureus</i> . <u>Clarification provided</u> <i>Monascus purpureus</i> .	Controllo dei livelli ematici di colesterolo. <u>Clarification provided</u> Cholesterol management / heart health.	Aiuta a controllare i livelli ematici di colesterolo nell'ambito di una dieta globalmente controllata. <u>Clarification provided</u> <i>Monascus purpureus</i> helps to decrease blood cholesterol levels through balanced diet.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Monacoline equivalent to 3 mg per day.</li> </ul>		



**GLOSSARY AND ABBREVIATIONS**

HMG-CoA	3-hydroxy-3-methylglutaryl-coenzyme A
ITT	Intention to treat
LDL	Low density lipoproteins
PP	Per protocol
RCT	Randomised controlled trial